

§ 158.330

(A) Each brand name, trade name, or other commercial designation of the starting material.

(B) The name and address of the person who produces the starting material or, if that information is not known to the applicant, the name and address of each person who supplies the starting material.

(C) All information that the applicant knows (or that is reasonably available to him), concerning the composition (and if requested by the Agency, chemical or physical properties) of the starting material, including a copy of all technical specifications, data sheets, or other documents describing it.

(3) The information required by paragraph (a)(2) of this section concerning each inert ingredient.

(c) *Additional information.* On a case-by-case basis, the Agency may require additional information on substances used in the production of the product.

§ 158.330 Description of production process.

If the product is produced by an integrated system, the applicant must submit information on the production (reaction) processes used to produce the active ingredients in the product. The applicant must also submit information about the formulation process, in accordance with § 158.335.

(a) Information must be submitted for the current production process for each active ingredient that is not derived from an EPA-registered product. If the production process is not continuous (a single reaction process from starting materials to active ingredient), but is accomplished in stages or by different producers, the information must be provided for each such production process.

(b) The following information must be provided for each process resulting in a separately isolated substance:

(1) The name and address of the producer who uses the process, if not the same as the applicant.

(2) A general characterization of the process (e.g., whether it is a batch or continuous process).

(3) A flow chart of the chemical equations of each intended reaction occurring at each step of the process, and of

40 CFR Ch. I (7–1–12 Edition)

the duration of each step and of the entire process.

(4) The identity of the materials used to produce the product, their relative amounts, and the order in which they are added.

(5) A description of the equipment used that may influence the composition of the substance produced.

(6) A description of the conditions (e.g., temperature, pressure, pH, humidity) that are controlled during each step of the process to affect the composition of the substance produced, and the limits that are maintained.

(7) A description of any purification procedures (including procedures to recover or recycle starting materials, intermediates or the substance produced).

(8) A description of the procedures used to assure consistent composition of the substance produced, e.g., calibration of equipment, sampling regimens, analytical methods, and other quality control methods.

§ 158.335 Description of formulation process.

The applicant must provide information on the formulation process of the product (unless the product consists solely of a technical grade of active ingredient) as required by the following sections:

(a) Section 158.330(b)(2), pertaining to characterization of the process.

(b) Section 158.330(b)(4), pertaining to ingredients used in the process.

(c) Section 158.330(b)(5), pertaining to process equipment.

(d) Section 158.330(b)(6), pertaining to the conditions of the process.

(e) Section 158.330(b)(8), pertaining to quality control measures.

§ 158.340 Discussion of formation of impurities.

The applicant must provide a discussion of the impurities that may be present in the product, and why they may be present. The discussion should be based on established chemical theory and on what the applicant knows about the starting materials, technical grade of active ingredient, inert ingredients, and production or formulation process. If the applicant has reason to believe that an impurity that EPA

would consider toxicologically significant may be present, the discussion must include an expanded discussion of the possible formation of the impurity and the amounts at which it might be present. The impurities which must also be discussed are the following, as applicable:

(a) *Technical grade active ingredients and products produced by an integrated system.* (1) Each impurity associated with the active ingredient which was found to be present in any analysis of the product conducted by or for the applicant.

(2) Each other impurity which the registrant or applicant has reason to believe may be present in his product at any time before use at a level ≥ 0.1 percent (1,000 ppm) by weight of the technical grade of the active ingredient, based on what he knows about the following:

(i) The composition (or composition range) of each starting material used to produce his product.

(ii) The impurities which the applicant knows are present (or believes are likely to be present) in the starting materials, and the known or presumed level (or range of levels) of these impurities.

(iii) The intended reactions and side reactions which may occur in the production of the product, and the relative amounts of byproduct impurities produced by such reactions.

(iv) The possible degradation of the ingredients in the product after its production but prior to its use.

(v) Post-production reactions between the ingredients in the product.

(vi) The possible migration of components of packaging materials into the pesticide.

(vii) The possible carryover of contaminants from use of production equipment previously used to produce other products or substances.

(viii) The process control, purification and quality control measures used to produce the product.

(b) *Products not produced by an integrated system.* Each impurity associated with the active ingredient which the applicant has reason to believe may be present in the product at any time before use at a level ≥ 0.1 percent (1,000

ppm) by weight of the product based on what he knows about the following:

(1) The possible carryover of impurities present in any registered product which serves as the source of any of the product's active ingredients. The identity and level of impurities in the registered source need not be discussed or quantified unless known to the formulator.

(2) The possible carryover of impurities present in the inert ingredients in the product.

(3) Possible reactions occurring during the formulation of the product between any of its active ingredients, between the active ingredients and inert ingredients, or between the active ingredient and the production equipment.

(4) Post-production reactions between any of the product's active ingredients and any other component of the product or its packaging.

(5) Possible migration of packaging materials into the product.

(6) Possible contaminants resulting from earlier use of equipment to produce other products.

(c) *Expanded discussion.* On a case-by-case basis, the Agency may require an expanded discussion of information on impurities:

(1) From other possible chemical reactions.

(2) Involving other ingredients.

(3) At additional points in the production or formulation process.

§ 158.345 Preliminary analysis.

(a) If the product is produced by an integrated system, the applicant must provide a preliminary analysis of each technical grade of active ingredient contained in the product to identify all impurities present at 0.1 percent or greater of the technical grade of the active ingredient. The preliminary analysis should be conducted at the point in the production process after which no further chemical reactions designed to produce or purify the substances are intended.

(b) Based on the preliminary analysis, a statement of the composition of the technical grade of the active ingredient must be provided. If the technical grade of the active ingredient cannot